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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------|-------------|----------------------|-----------------------|------------------|
| 10/615,484 | 07/08/2003 | Alan R. Fritzberg | 295.034US1 | 8966 |
| 21186 | 7590 | 10/27/2005 | EXAMINER | |
| SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH | | | JONES, DAMERON LEVEST | |
| 1600 TCF TOWER | | | ART UNIT | PAPER NUMBER |
| 121 SOUTH EIGHT STREET | | | | 1618 |
| MINNEAPOLIS, MN 55402 | | | | |

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/615,484 | FRITZBERG, ALAN R. |
| | Examiner | Art Unit |
| | D. L. Jones | 1618 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 August 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-58 and 60-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1-58 and 61-63 is/are allowed.
- 6) Claim(s) 60 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 8/5/05.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 8/5/05 wherein claim 59 is canceled.

Note: Claims 1-58 and 60-63 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS

2. The Applicant's arguments filed 8/5/05 to the rejection of claim 60 made by the Examiner under 35 USC 112 have been fully considered and deemed non-persuasive for the reasons set forth below.

112 Second Paragraph Rejection

The rejection of claim 60 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 6/16/05 and those set forth below.

In summary, Applicant asserts that it is known in the art that bone marrow ablation and stem cell transplantation are used together to treat hematologic cancer or genetic disorders, including storage disease, hemoglobinopathies, or severe immunodeficiency. Thus, Applicant cited three websites and US Patent No. 6,767,531. Hence, ***Applicant concluded that one would have no difficulty in determining what conditions beyond those disclosed in Applicant's specification that are encompassed by claim 60 as written.***

All of Applicant's arguments have been considered and found non-persuasive.

First, review of the article from one of the websites (www.oncolink.com) submitted by Applicant to indicate that it is known in the art that bone marrow ablation and stem cell transplantation are used together to treat hematologic cancer or genetic orders, illustrates that while hematopoietic stem cells can be modified to engraft within a host, the hope is that some day, the procedure may be used to treat adults who must undergo bone marrow ablation for treatment of cancer or other major hematologic disorder. Thus, the article submitted to illustrate that one of ordinary skill in the art would have no difficulty in determining what conditions beyond those disclosed in the specification are encompassed by claim 60 is not consistent with the teachings of the art which has been made of record, date 2004 which is a year or so after Applicant's filing date. Hence, one of ordinary skill in the art would not know what conditions are encompassed by Applicant's claim 60.

Secondly, Applicant is reminded that the purpose of 35 USC 112, second paragraph, is to aid Applicant in summarizing information from the specification with one or more claims by particularly point out and distinctly claiming the subject matter *which the Applicant regards as his invention*. Thus, Applicant is entitled to that which is his invention and supported by the specification, not that which could possibly later be encompassed by the specification, or that which what Applicant did not have possession of at the time of failing. Hence, the claim as written is indefinite because it is unclear what treatable conditions Applicant is referring to. Once again, it is respectfully requested

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that Applicant clarify the instant invention in order that one may ascertain what is being claimed.

Note: The second document submitted by Applicant (Combination Chemotherapy Followed by Donor Bone Marrow Transplantation or Peripheral Stem Cell Transplantation in Treating Patients with Hematologic Cancer or Genetic Disorders) obtained from the website www.clinicaltrials.gov submitted by Applicant to indicate that it is known in the art that bone marrow ablation and stem cell transplantation are used together to treat hematologic cancer or genetic disorders has been reviewed. The document discloses that the rationale for the study is that peripheral stem cell transplantation or bone marrow transplantation may be able to replace immune cells that were destroyed by chemotherapy used to kill tumor cells. However, the outcome of the study was not available. Thus, whether the goals of the study were achieved are unclear.

112 First Paragraph Rejection

The rejection of claim 60 under 35 USC, first paragraph, because the specification, while being enabling for conditions treatable with stem cell transplantation, with or without gene therapy, that utilize bone marrow ablation such as sickle cell anemia and lysosomal and peroxisomal storage diseases, does not reasonably provide enablement for all conditions treatable with stem cell transplantation, with or without gene therapy, is MAINTAINED for reasons of record in the office action mailed 6/16/05 and those set forth below.

In summary, Applicant's asserts that the Examiner's conclusions in regards to the In re Wands factors appear to be doubts unsubstantiated by evidence or technical reasoning, and appear to be mere conclusions coupled with stereotyped expression.

First, in regards to Applicant not being entitled to all conditions treatable with stem cell transplantation, with or without gene therapy, except those set forth in the disclosure, Applicant is reminded that an inventor is entitled to a patent to protect his/her invention only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. As a result, the inventor must be able to describe (i.e., by properly written claims) the invention with such clarity that the reader is assured that the inventor actually has possession and knowledge of the invention that makes it worthy of patent protection. The instant invention does not do that. What one observes from claim 60 is a desire, plan, or first step for obtaining a desired result. While it is appreciated that the inventor had a goal for achieving a certain end result, establishing goals is not the basis for issuing a patent. One must proceed to do what is necessary to accomplish the desired end. Secondly, in support of the Examiner's position in regards to the 112, first paragraph, rejections, and documents not being of record as evidence that Applicant is not entitled to all conditions other than those set forth above, the documents submitted by Applicant are applicable. In particular, the documents illustrate hypotheses, but do not disclose with certainty the end result desired by Applicant, that the specific conditions were definitely treatable (see the discussion above under '112

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Second Paragraph Rejection'). Hence, it cannot be concluded that all stem cell transplantation conditions are treatable with the composition of the instant invention.

COMMENTS/NOTES

3. It is once again noted that claims 1-58 and 61-63 are allowable over the prior art of record for reasons of record in the office action mailed 7/24/04.

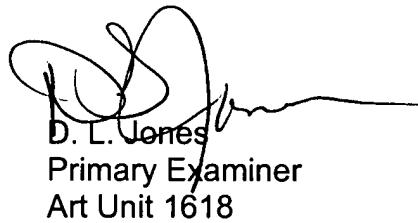
4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
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October 24, 2005